C. The Defendant Drug Manufacturers' Use of AWP Fraud to Increase and Maintain the Price of Drugs Outside of the Medicare Part B Context

181. The Defendant Drug Manufacturers' AWP fraud strikes well beyond Medicare Part B, adversely impacting health plans and their participants with respect to reimbursements for scores of other drugs. As described below, one such area is the use of AWPs by PBMs.

182. Health plans typically contract with intermediaries called pharmacy benefit managers ("PBMs") so that a health plan's participants can obtain brand name drugs from pharmacies or, via mail order, directly from the PBMs. In these contracts, the brand name drugs are priced at the AWP less a certain percentage "discount."

183. Pharmacy benefit managers – or "PBMs" – are fiscal intermediaries that specialize in the administration and management of prescription benefit programs. PBM clients include HMOs, employers, preferred provider organizations and other health insurers. Collectively, four PBMs comprise the significant market share of the PBM market. They are: AdvancePCS; Caremark; Express Scripts; and Medco Health. These four companies handle the drug benefits of 210 million people in the United States, or 70 percent of the nation's population.

184. For brand name drugs, PBMs use inflated "Average Wholesale Price" – or "AWP" – set by drug manufacturers as the basis for reimbursement (i) made by health plans to the PBMs for their members' drug purchases; and (ii) from the PBMs to the pharmacies for the purchases made by health plans' members. The PBMs typically contract with retail pharmacies to reimburse an amount equal to each drug's AWP, less a specified discount, plus a dispensing fee. Because the PBMs consider the contracting relationship with retail pharmacies to be confidential, health plans are never informed of the reimbursement amount to pharmacies. However, the PBM frequently pockets a "spread" or differential between charges paid to pharmacies and collected from clients. So, for example, clients may be charged the AWP minus 13 percent, but the retail pharmacy may only receive the AWP minus 15 percent, generating an undisclosed 2 percent spread for the PBM. Furthermore, as the example presented demonstrates,

PBMs are motivated to, and do place on their formulary those drugs with inflated AWPs: the greater the AWP inflation, the greater the profit to the PBM based on the 2 percent spread. A similar situation occurs for generic drug pricing based on Maximum Acquisition Cost ("MAC") lists, as the PBM uses one MAC list to charge clients and another MAC list to reimburse pharmacies. Further, with respect to mail order prescriptions, PBMs do business with companies that have the right to repackage drugs; they are called repackagers. These repackagers assign a new NDC number to a drug and publish a higher AWP. The PBM then negotiates with the repackager a discount off the AWP and tells the health plan it has saved a certain percentage off the AWP. But because the repackager's AWP is higher, the health plan pays more and the PBM pockets the spread between the AWP and the price paid to the repackager. PBMs also have mail order services in which case they act as the pharmacy. In this situation, the PBM keeps the spread between the AWP and the list price as there is no intermediary, like a pharmacy dispensing the drug. The PBMs keep this spread knowing that the AWPs are inflated and not the true AWP.

185. The Defendant Drug Manufacturers knew and understood that the PBM Defendants used the *Red Book* and other publications to determine the AWPs of the drugs. Because the drug manufacturers controlled the AWPs published in the *Red Book* and other compendia, the drug manufacturers knew and understood that they could help manipulate the PBMs' profits from Plaintiffs and the classes. The purpose of artificially inflating the PBMs' profits was to create an illegal kickback to the PBMs, funded by health plan and subscriber overpayments.

186. PBMs use the inflated AWPs set by drug manufacturers as the basis for the payments (i) made by health plans to the PBMs for their members' drug purchases, and (ii) from the PBMs to the pharmacies for the purchases made by health plans' members.

187. The PBMs typically contract with retail pharmacies to reimburse in an amount equal to each drug's AWP, less a specified discount, plus a dispensing fee. Because the PBMs consider the contracting relationship with retail pharmacies to be confidential, health plans are never informed of the reimbursement amount to pharmacies.

188. However, the PBMs frequently pockets a secret "spread" or differential between charges paid to pharmacies and collected from clients. So, for example, clients may be charged the AWP minus 13 percent, but the retail pharmacy may only receive the AWP minus 15 percent, generating an undisclosed 2 percent spread for the PBMs.

189. Furthermore, as the example presented demonstrates, PBMs are motivated to place on their formulary those drugs with inflated AWPs: the greater the AWP inflation, the greater the profit to the PBM based on the 2 percent spread.

190. A similar situation occurs for generic drug pricing based on MAC lists, as the PBM uses one MAC list to charge clients and another MAC list to reimburse pharmacies.

191. The PBMs deliberately utilize the inflated AWP to overcharge health plans for brand name drugs purchased by their participants and beneficiaries at retail pharmacies. An example of this practice was recently reported in the WALL STREET JOURNAL on March 30, 2003. According to the JOURNAL article, the AWP for fluoxetine is $2.66 a pill. With a 60 percent discount off the AWP, that brings the price to $1.06 a pill the PBM collects from the plan. Express Scripts pays the pharmacy 25 cents a pill and keeps the rest as profit. Express Scripts claims that currently its client pays 60 cents a pill, but since Express Scripts pays a pharmacy 25 cents per pill, it receives almost a 100 percent profit. And at the same time it was making this profit, Express Scripts was notifying its clients it was saving them money by having switched to fluoxetine, instead of Prozac.

D. The Defendant Drug Manufacturers' Use of AWP Fraud to Increase and Maintain Volume and Market Share For Generic and Multi-Source Drugs

192. The Defendant Drug Manufacturers' AWP fraud is most exacerbated for generic drugs or for brand name drugs for which there are biological or therapeutic equivalents.

193. Health plans and other sponsors of drug benefits contract with PBMs both so that the plan's participants can obtain ***brand name*** drugs from pharmacies or mail order distribution, but also so that they might receive ***multi-source***, or ***generic, drugs***. As with brand name drugs, reimbursement for multi-source, or generic, drugs is also related to a published average wholesale price for each generic drug manufactured and/or distributed by a generic drug company.

194. In the private payor arena, generic drug reimbursement is determined either in the same manner for brand name drugs (*i.e.*, a certain percentage "discount" off of the AWP), or is based on the amount specified as the maximum allowable cost or "MAC." MAC prices or reimbursements rates are a schedule of pricing for generically equivalent drugs based upon the listed average wholesale prices (AWPs) of competing generic drug manufacturers. The federal government originally introduced the concept of MAC reimbursement for generic medications. The CMS issues a MAC price list for generic products that have three or more manufacturers or distributors on the market. Because of this limitation, not all generics have a corresponding CMS MAC price.

195. PBMs often utilize this government-issued MAC reimbursement publication as a basis for their proprietary MAC list and supplement the list with other generic products or modify it for a variety of purposes. Sometimes, to stabilize the cost variance of different generic products of the same compound, pharmacy benefit administrators calculate a maximum allowable cost based on the list average wholesale prices of competing generic drug manufacturers (indeed, this is termed in the industry as the average average wholesale price or

"AAWP"). The resulting proprietary MAC generic drug reimbursement lists are typically based on the AAWP and, in turn, the AWP.

196. Accordingly, in the private payor arena generic drug reimbursement is closely tied to the published AWP for a generic drug. Generic drug makers are able to push market share for their generic drugs by intentionally increasing the published AWP for a generic drug with the intention to create a profit margin for others in the distribution chain. That profit margin is taken advantage of either directly (through reimbursement based upon the AWP for some plans and in some channels) or indirectly on the AWP based upon the establishment of a MAC tied to the AWP.

197. In the public payor arena under Medicare Part B, multi-source drugs or biologicals are also reimbursed on the basis of AWP. For multi-source drugs or biologicals, under Medicare Part B the AWP is equal to the lessor of the median AWP of all of the generic forms of the drug or biological, or the lowest brand name product AWP. Because reimbursement is pegged to the AWP, drug makers act in unison by elevating the AWP for all generic drugs, thereby inflating the amount of the reimbursement that occurs through Medicare Part B, including the Medicare co-payment through Part B.

198. As stated by one industry consultant:

> . . . This situation is more pronounced with generic drugs. Many generic companies have taken advantage of this use of AWP by substantially inflating their published AWPs.. . . [T]he system allows a retailer to acquire a drug at a low cost $2.50 per 100 tablets, for example) while relying on a published AWP ($20.00 or more) for its own pricing. It is not uncommon that the $25.00 retail price for a generic drug renders a gross profit well above $20.00 for the retailer. It is also common for the AWP of a generic product to remain stable while the actual selling price declines. . . .It is obvious that AWP is not an accurate measure of the prices manufactures charge. It must also be noted that not all generic products will be priced similarly. Some, in fact, use the more traditional method of a 20% markup to reach an AWP. This can be a handicap for generic companies choosing this method because retailers often use the AWP as the starting point for many pricing

decisions and an artificially high AWP provides the retailer with greater profits.

199. The raising of an individual Defendant's reported AWP for a multi-source drug raises the median AWP at which the generic drug is reimbursed. As a result, the publication and reporting of fraudulent AWPs by Defendants for generic drugs squarely fits generic drugs in which the cure of unlawful AWP inflation within the activity complained of in the MCC. Moreover, while any one generic manufacturer can only effect the median generic reimbursement AWP for a product, Defendants can and do create a spread between the median AWP and the actual prices paid by reporting AWPs that are far in excess of the actual wholesale prices while simultaneously maintaining or lowering actual wholesale prices.

200. Documents produced by Defendant generic manufacturers show that they are aware of the AWPs reported by their competitors and of the actual sales price of their generic competitors and that they manipulate their own AWPs in order to gain or maintain a competitive advantage in the market for their generic products. Each Defendant generic maker or distributor competes by inflating its AWP and thereby inflating the median AWP. The natural and expected result of this "leap frogging" of increasing AWPs is that multi-source drugs have some of the highest spreads of any drugs, sometimes resulting in an AWP over 50,000% over actual costs. A few examples are set forth below:

Defendant	Multisource Drug	*RedBook* AWP	DOJ Determined Actual AWP	Percentage Spread
Abbott	Sodium Chloride	$670.89	$3.22	20,735%
Baxter	Dextrose	$928.51	$2.25	41,167%
Baxter	Sodium Chloride	$928.51	$1.71	54,199%
BMS Group	Etoposide (Vepesid)	$136.49	$34.30	298%
Dey	Albuterol Sulfate	$30.25	$9.17	230%
Immunex	Leucovorin Calcium	$137.94	$14.58	846%
Pharmacia	Etoposide	$157.65	$9.47	1,565%
Sicor Group	Tobramycin Sulfate	$342.19	$6.98	4,802%
Watson	Vancomycin HCL	$70.00	$3.84	1,567%

201. In summary, generic or multi-source drugs are subject to fraudulent AWP manipulation as set forth in this Amended MCC.

202. The importance of AWPs to generic drugs was recently revealed in a lawsuit filed by Dey and two of the Publishers. In this lawsuit, Dey's allegations can be summarized as follows:

(a) Dey is a generic manufacturer, and generic manufacturers largely compete on price because they market products that contain the same active ingredients and are predominantly therapeutically interchangeable. (¶ 9 of Dey Complaint.)

(b) A large segment of the generic marketplace for respiratory drugs is comprised of a relatively small number of entities controlling purchase decisions. (¶ 12 of Dey Complaint.)

(c) The vast majority of prescription drug transactions – as much as 85% – are covered, in whole or in part, by third-party payor reimbursement arrangements such as managed care plans and Medicaid. (¶ 13 of Dey Complaint.) Both Medicaid and the private insurance system rely on reimbursement formulas that utilize the AWP. (¶¶ 14-16 of Dey Complaint.) ***This allegation confirms Plaintiffs' allegations in this Complaint that the AWP fraud impacts private markets, not just Medicaid.***

(d) Dey has an agreement with First DataBank and Medi-Span to provide the reporting services with AWP pricing information. Pursuant to this agreement (and in order to make Dey's products eligible for reimbursement through Medicaid Programs), Dey has reported WACs and AWPs. (¶¶ 26-32 of Dey Complaint.)

> In each case, until the events that have resulted in the present crisis, First DataBank has (except for some inadvertent errors) selected for listing in its published reports the AWP as suggested by Dey. For over ten years, until April 2003, no prices other than those submitted by Dey have been listed by First DataBank as AWP for Dey products in its databases [even though Dey also reported declining WACs for the products]."

(¶ 32 of Dey Complaint; *see also* ¶ 36 of Dey Complaint for similar allegation against Medi-Span.) This has also been the course of dealings between the Publishers and Dey's competitors:

> Virtually every drug manufacturer who participates in these reimbursement programs, and against whom Dey competes also communicates their suggested AWP prices to the reporting services. To the best of Dey's knowledge, with few, if any exceptions, First DataBank and Medi-Span have selected and reported the AWP pricing exactly as suggested by these competing manufacturers.

(¶ 37 of Dey Complaint.) *See also* ¶ 47 of Dey Complaint (recounting testimony of First DataBank representative who admits that First DataBank had always accepted the AWPs suggested by the manufacturers).

(e) Providers who dispense generic drugs "are cognizant of, and are highly attentive to, AWPs as reported by the recognized industry compendia published by First DataBank and Medi-Span because of the direct relationship between the level of reimbursement anticipated for the drugs selected and the reported AWPs of those drugs." (¶ 38 of Dey Complaint.) Indeed, Dey admits that it has relied on the publishers' practice of treating all manufacturers equally by simply reporting whatever AWP a manufacturer submitted. Consequently, First DataBank and Medi-Span have frustrated Dey's "reasonable expectations" by ***independently reporting*** an AWP different than that submitted by Dey. (¶ 39 of Dey Complaint.) These allegations become even more emphatic in a section of the Complaint titled "The Immediate Consequences of the Arbitrary Changes:"

> Since reimbursement to Dey's customers is, in Medicaid program in many states and in and [sic] insurance programs, most frequently based on the AWP as reported by the reporting services, this arbitrary and capricious reduction by First DataBank and Medi-Span in AWP would result in a drastic reduction in the reimbursement to drug providers who choose to dispense Dey's product. Since there has not been a comparable reduction in the AWP for Dey's competitors, there would be no comparable reduction in the reimbursement the purchasers of competitive products receive.

> Because reimbursement for Dey products would be significantly reduced, but reimbursement for those competing products would remain as they have been, Dey is prevented, by First DataBank's and Medi-Span's arbitrary and capricious acts, from effectively competing in the marketplace.
>
> In fact, within one day of learning that First DataBank and Medi-Span had arbitrarily changed Dey's AWP, Dey has already been contacted by at least nine of its customers complaining about the drastic changes and indicating that, because of those changes, the customers would not be able to purchase Dey products since they could not earn a reasonable profit from the sale of such products.
>
> Further, at least one customer has already indicated that he had canceled all of his purchases presently on order from Dey and was, instead, buying those products from Dey's direct competitors.
>
> ….. These providers will cease to purchase and dispense Dey's drugs if the reimbursement for those drugs is a fraction of those obtained from competing companies. Because purchasing decisions are highly concentrated in this industry among wholesalers and group purchasing organizations, this scenario is playing out across the country and threatens to eliminate sales of Dey's products that are covered by Medicaid and insurance reimbursement programs.

(¶¶ 50-54 of Dey Complaint.)

203. ***These allegations confirm the allegations herein that medical providers rely on spreads in dispensing (and, consequently, so do the manufacturers in order to move market share).*** Further, these allegations are akin to saying: "We all committed fraud on an even basis, but now only my competitors can commit fraud; consequently, I have now suffered damage."

E. Defendants' Concealment of the Truth

204. Each Defendant concealed its fraudulent conduct from the Plaintiffs and the Class by controlling the process by which the AWPs for Covered Drugs and brand name drugs were set. Defendants prevented Plaintiffs and the Class Members from knowing what the actual pricing structures for these drugs were, and failed to inform them of the usage of free samples and the provision of other financial incentives to providers and other intermediaries to lower their respective costs for the drugs. Moreover, Defendants' fraudulent conduct was of such a nature as to be self-concealing.

205. Each Defendant closely guarded its pricing structures and sales figures for their Covered Drugs and brand name drugs. CMS Health Care Industry Market Update (dated January 10, 2003) stated that drug "price discounts are closely guarded as competitive information." *See* p. 39.

206. Each Defendant also concealed its fraudulent conduct by instructing providers and others not to report the prices they paid for the Covered Drugs and brand name drugs, respectively.

207. Each Defendant also worked with and motivated provider and intermediary trade associations to halt any investigations or change in the AWP system.

208. Each Defendant's efforts to conceal its pricing structures for Covered Drugs and brand name drugs is evidence that it knew that its conduct was fraudulent.

209. Thus, each Defendant concealed that (i) its AWPs were highly-inflated (and were inflated solely to cause Plaintiffs and the Class to overpay for the AWPIDs), (ii) it was manipulating the AWPs of the AWPIDs, and (iii) the AWPs bore no relationship to the prices paid for, or the pricing structure of, the AWPIDs as they were sold to providers and others.

210. Plaintiffs were diligent in pursuing an investigation of the claims asserted in this Complaint. Through no fault of their own, they did not receive inquiry notice nor learn of the factual basis for their claims in this Complaint and the injuries suffered therefrom until recently.

F. Tolling of Applicable Statutes of Limitation

211. Any applicable statutes of limitations have been tolled by Defendants' knowing and active concealment and denial of the facts alleged herein. Plaintiffs and members of the Class have been kept in ignorance of vital information essential to knowledge of and the pursuit of these claims, without any fault or lack of diligence on their part. Plaintiffs and members of the Class could not reasonably have discovered the fraudulent nature of the published AWPs.

212. Defendants were and continue to be under a continuing duty to disclose to Plaintiffs and the Class the fact that the published AWPs bore and continue to bear no relationship to the prices or pricing structures for Covered Drugs and brand name drugs. Because of their knowing, affirmative, and/or active concealment of the fraudulent nature of the published AWPs, Defendants are estopped from relying on any statutes of limitations.

V. EXAMPLES OF SPECIFIC UNLAWFUL CONDUCT

213. Due to acts of concealment by each Defendant, the following examples of the specific unlawful conduct engaged in by each particular Defendant are merely illustrative. They are not intended to be an exhaustive account of all of the unlawful activity engaged in by each Defendant. Instead, these allegations allege the circumstances of the wrongdoing with some detail. Additional detail is peculiarly within the Defendants' control and warrants that further discovery should proceed as to each drug identified in this Complaint as well as other drugs whose AWP is published by any Defendant.

A. Abbott

214. Abbott engages in an organization-wide and deliberate scheme to inflate AWPs. Abbott has stated fraudulent AWPs for all or almost all of its drugs, including those set forth below. The specific drugs of Abbott for which relief is currently sought in this case are set forth in Appendix A or in the proposed class certification order, and are summarized below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
ABBOTT	A-Methapred	methylprednisolone sodium succinate	Anti-Inflammatory Agent Used to provide relief for inflamed areas of the body. Also used for control of allergic processes
	Aminosyn	amino acid	Nitrogen Product Used as a nutritional supplement
	Biaxin	clarithromycin	Macrolide (Anti-Infective Agent) Used to treat mild to moderate infections
	Calcijex	calcitrol	Hormone Used in the treatment of hypocalcemia

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Depakote	divalproex sodium	Anticonvulsant Used in the treatment of complex partial seizures
	Ery-tab	erythromycin, enteric-coated	Antibiotic Agent (Anti-Infective Agent) Used in the treatment of various infections
	Erythromycin	erythromycin base	Antiacne Agent; Anti-Infective Agent Used in the treatment of various infections
	Liposyn II	fat emulsion	Caloric Agent; Nutritional Supplement Used as a nutritional supplement
	Prevacid	lansoprazole	Proton Pump Inhibitor (Gastrointestinal Agent) Used in the treatment of duodenal ulcer and erosive esophagitis
		acetylcysteine	Mucolytic (Respiratory Agent: Diagnostic Aid) Used for certain lung conditions when increased amounts of mucus make breathing difficult
		acyclovir sodium	Anti-Infective Agent Used in the treatment of herpes infections
		amikacin sulfate	Antibiotic Agent (Anti-Infective Agent) Used to treat respiratory tract, urinary tract, bone, skin and soft tissue infections
		cimetidine hydrochloride	Gastrointestinal Agent Used in the treatment of duodenal ulcer and prevention of ulcer recurrence
		clindamycin phosphate	Anti-Infective Agent Used in the treatment of vaginal infections
		dextrose	Caloric Agent Used to increase intake of calories and fluids
		dextrose sodium chloride	Caloric Agent; Electrolyte Replenisher Used to increase intake of calories and fluids
		diazepam	Central Nervous System Agent Used to treat status eplipeticus and anxiety disorders. Also used as an amnesic prior to surgical procedures
		fentanyl citrate	Central Nervous System Agent Used for anesthetic purposes
		furosemide	Diuretic Used in the treatment of edema associated with cirrhosis and kidney disease. Also used to manage hypertension

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
		gentamicin sulfate	Anti-Infective Agent Used as a general antibiotic to treat serious gastrointestinal, respiratory, bone, skin and soft tissue infections
		heparin sodium or heparin lock flush	Blood Modifier Used to prevent and treat thrombosis and pulmonary embolism. Also used as an anticoagulant in blood transfusions and dialysis procedures
		leucovorin calcium	Antianemic Agent (Blood Modifier) Used in the treatment of anemia
		lorazepam	Central Nervous System Agent Used in the treatment of anxiety disorders
		sodium chloride	Flush; Abortifacient Used to remove medicine and blockage from intravenous (IV) catheter. Also used to induce abortion
		tobramycin sulfate	Antibiotic Agent (Anti-Infective Agent) Used to treat severe infection
		vancomycin hydrochloride	Antibiotic Agent (Anti-Infective Agent) Used as a general antibiotic

1. Abbott Has Been The Target of Government Investigations

215. In connection with its scheme to inflate AWPs, Abbott has been investigated by the United States Department of Justice, Commonwealth of Massachusetts, the Office of Inspector General of the Department of Health and Human Services, the Attorney General for the State of Texas, the Attorney General for the State of California, and the State of California Department of Justice Bureau of Medi-Cal Fraud and Elder Abuse.

216. These investigations confirm that Abbott has engaged in a deliberate scheme to inflate the published AWPs for many of its drugs. According to Representative Pete Stark, the ranking member of the Congressional Ways and Means Committee:

> The price manipulation scheme is executed through Abbott's inflated representations of average wholesale price ("AWP") and direct price ("DP") which are utilized by the Medicare and Medicaid programs in establishing drug reimbursements to providers. The difference between the inflated representations of AWP and DP versus the true price providers are paying, is

> regularly referred to . . . as "the spread." The evidence . . . clearly shows that Abbott has intentionally reported inflated prices and has engaged in other improper business practices in order to cause its customers to receive windfall profits from Medicare and Medicaid when submitting claims for certain drugs. The evidence further reveals that Abbott manipulated prices for the express purpose of expanding sales and increasing market share of certain drugs. This was achieved by arranging financial benefits or inducements that influenced the decisions of health care providers submitting Medicare and Medicaid claims.

See October 31, 2000 letter from U.S. Representative Pete Stark to Miles White, Chief Executive Officer of Abbott. (P007647-78.)

2. Abbott Controls the Published AWP for Its Products

217. Abbott has controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period.

3. Abbott's AWP Manipulation Benefited Providers at the Expense of the Class

218. The purpose of Abbott's manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries at the expense of Plaintiffs and the Class.

a. For example, Abbott anticipated that the spread between AWP and cost would be eliminated by legislative changes in 1997. Accordingly, Abbott looked for ways to maximize the profit spread immediately. In one internal memorandum about a third party's pricing product, Abbott states:

> One of GeriMed's goals of obtaining maximum profitability for its members presents an opportunity for our injectables. They think there is about an 18 month window of opportunity to promote our injectables as more profitable for their members to use because of the bigger spread between AWP and cost. Legislative changes in reimbursement are expected to do away with this spread advantage by mid 1997.

(ABT AWP/MDL 015839) (Highly Confidential).

b. In a second memorandum about this same product, Abbott states:

> The purpose of these programs was to "enhance revenue and decrease cost." *** These suggestions are made to save money through lower contract pricing or increase revenue through better spread between AWP and contract price.... The [distributor's] program identifies the lowest cost product and ***the best spread for the particular state***.

(ABT AWP/MDL 010407-09) (Highly Confidential) (emphasis added).

219. Abbott tried to maximize spread because it understood that its customers routinely engaged in "spread shopping" – comparing Abbott's AWPs with those of its competitors in order to determine the greatest spread (and therefore sell or administer the drug with the greatest spread). An example is a document produced by Abbott, prepared by a customer in late 1993, comparing Abbott's proposed contract price and its published AWPs with that of Baxter's competing generic drugs. (ABT AWP/MDL 028546) (Highly Confidential).

220. Just as Abbott motivates providers to administer drugs based on the AWP, Abbott's 1996 Pricing Guidelines reveal that Abbott rewards PBMs based on the degree of influence they exert to drive utilization of Abbott products. (ABT AWP/MDL 053922-23) (Highly Confidential).

4. Specific Abbott AWPs Documented by the DOJ

221. In a report published by the DHHS (the "DHHS Report"; PM Rev. AB-00-86, "An Additional Source of Average Wholesale Price Data In Pricing Drugs and Biologicals Covered by the Medicare Program," Sept. 8, 2000), the DOJ documented at least 81 instances where the published AWPs for various dosages of 16 drugs manufactured by Abbott were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the 16 drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Abbott in the 2001 *Red Book*.

Drug	Abbott's 2001 *Red Book* AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Acetylcysteine	$35.87	$21.90	$13.97	64%
Acyclovir	$1047.38	$349.05	$698.33	200%
Amikacin Sulfate	$995.84	$125.00	$870.84	697%
Calcitriol (Calcijex)	$1,390.66	$1079.00	$311.66	29%
Cimetidine Hydrochloride	$214.34	$35.00	$179.34	512%
Clindamycin Phosphate	$340.52	$75.35	$265.17	352%
Dextrose	$239.97	$3.91	$236.06	6,037%
Dextrose Sodium Chloride	$304.38	$1.93	$302.45	15,671%
Diazepam	$28.50	$2.03	$26.47	1,304%
Furosemide	$74.52	$14.38	$60.14	418%
Gentamicin Sulfate	$64.42	$.51	$63.91	12,531%
Heparin Lock Flush	$38.30	$13.60	$24.70	182%
Metholprednisolone Sodium Succinate	$34.08	$2.30	$31.78	1,382%
Sodium Chloride	$670.89	$3.22	$667.67	20,735%
Tobramycin Sulfate	$150.52	$2.94	$147.58	5,020%
Vancomycin Hydrochloride	$382.14	$4.98	$377.16	7,574%

(P006299-316.)

5. Additional Evidence Concerning Vancomycin

222. At least one Publisher, Medi-Span, challenged the manner in which Abbott set its AWPs for vancomycin. The following statement appeared in a February 9, 1996 faxed letter to Abbott from a representative of Medi-Span:

> It appears that the only difference between these two products listed is the vial it comes in. If it is, please let us know why the $400 plus difference in AWPs?... [T]his customer claims he can get Vancomycin for $6 or $7 per vial DP as opposed to the $52.94 and $19.50 the Abbott Vancomycin cost.

(ABT AWP/MDL 001215.)

223. The government investigation into Abbott's AWP for vancomycin identified:

> prices that are routinely made available to many providers, but are far below Medicare reimbursement rates. They include 1999 prices for vancomycin, the Abbott Labs-manufactured antibiotic, which a health care provider could buy for $76.00 but for which the AWP upon which Medicare's reimbursement was based on was $261.84.

See September 25, 2000 letter from U.S. Rep. Tom Bliley to the Honorable Nancy-Ann Min DeParle, Administrator of the Health Care Financing Administration. (P007015-490.)

224. For other doses of vancomycin, Abbott reported an AWP of $68.77 as of April 2000. The DOJ adjusted it to $8.14.

6. Additional Evidence for Amikacin

225. One published report states: "Amikacin, used to treat an infection that HIV+ people get and manufactured by Abbott, had an AWP of $54.56. DOJ said the actual price was $6.75." *See States Mull Suit Against Drug Companies*, www.stateline.org (April 2, 2001) (P011268-70).

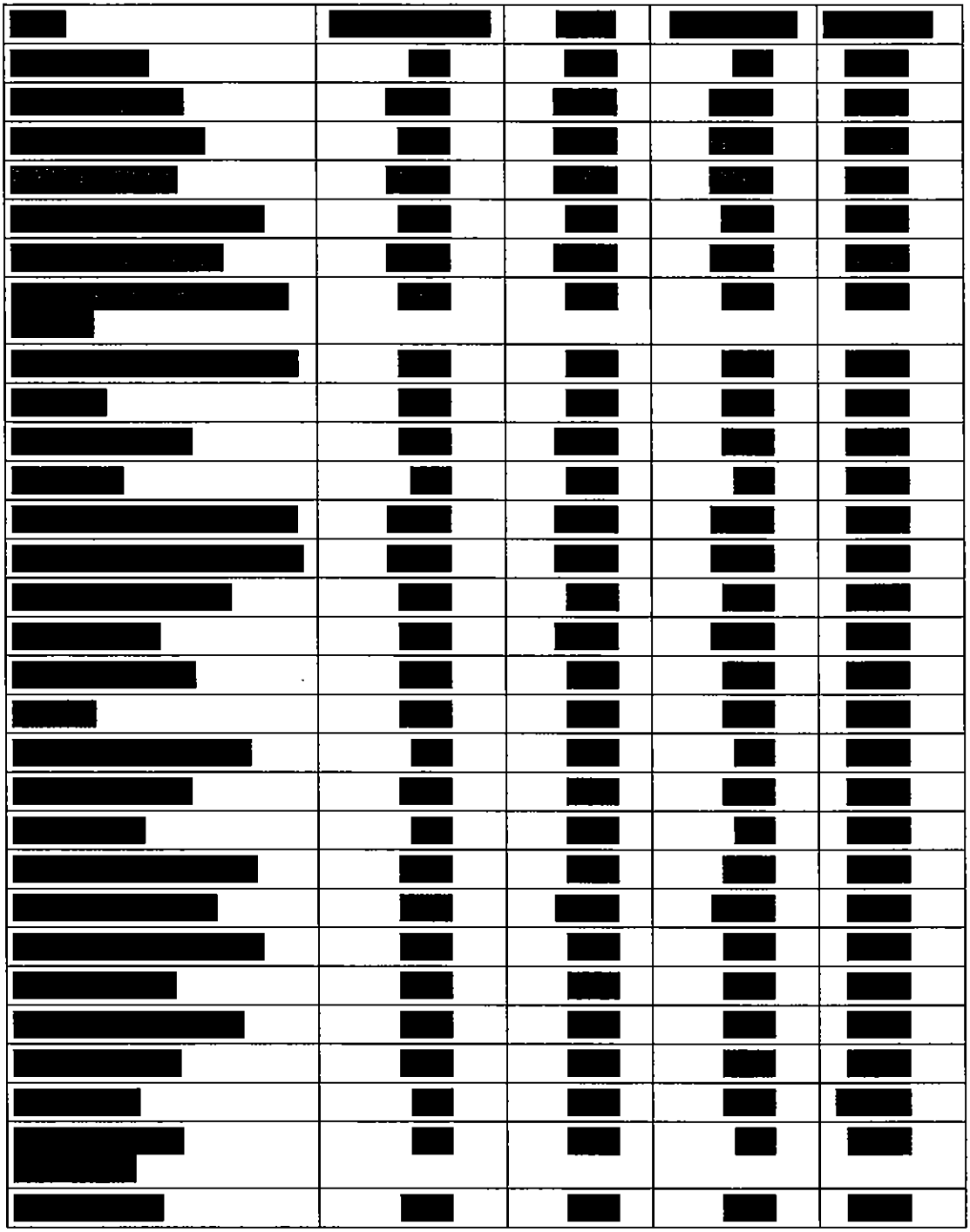
7. Inflated AWPs From Abbott Price Lists

226. In response to government subpoenas, Abbott produced numerous price lists setting forth spreads between AWPs and prices offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Abbott has consistently offered hundreds of its drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers. To repeat every one of those drugs and the spread offered to each specific customer here is not practical. However, set forth below in Tables 1 and 2 are a number of those drugs (not already referenced above) with spreads in excess of 100% from two specific Abbott customers.

227. [redacted]

[redacted]

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]



229. As set forth above, Abbott's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

B. Amgen

1. The Drugs at Issue and Their Competitive Environment

230. Amgen engages in an organization-wide and deliberate scheme to inflate AWPs. Amgen has stated fraudulent AWPs for all or almost all of its drugs, including: Epogen (eportin alfa for ESRD use),[1] Neupogen (filgrastim), Aranesp (darbepoetin alfa), Enbrel (etanercept), Kineret (anakrina), and Neulasta (pegfilgrastim). The specific drugs of Amgen for which relief is sought in this case are set forth in Appendix A and are set forth below and the complaint includes all NDCs for these drugs:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
AMGEN	Aranesp	darbepoetin alfa albumi	Antianemic Agent; Blood Modifier Used in the treatment of anemia associated with chronic renal failure and/or chemotherapy
	Enbrel	etanercept	Antirheumatic Agent Used to reduce signs and symptoms of rheumatoid arthritis
	Epogen	epoetin alfa	Antianemic Agent; Blood Modifier Used in the treatment of anemia associated with chronic renal failure, chemotherapy and/or HIV-infected patients
	Kineret	anakrina	Antirheumatic Agent Used in the treatment of moderate to severe rheumatoid arthiritis

[1] In the Medicare Part B context, reimbursement for Epogen is not based on the AWP, but rather on a specific dollar amount set by statute. However non-Medicare Part B reimbursement for Epogen is based on AWP for many Class members.

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Neulasta	pegfilgrastim	Antineoplastic; Blood Modifier Used to decrease incidence of infection (neutropenia) in some cancer patients
	Neupogen	filgrastim	Antineoplastic; Blood Modifier Used to decrease incidence of infection (neutropenia) in some cancer and leukemia patients

224A. Amgen introduced EPOGEN® (Epoeitin alfa) in 1989. EPOGEN® is indicated for the treatment of anemia in patients with chronic renal failure on dialysis. In 2001, Aranesp® (darbepoetin alfa), an erythropoietic protein with greater biological activity and a longer half-life than Epoetin alfa, was approved for the treatment of anemia in patients with chronic renal insufficiency. In 2002, Aranesp® was also approved for the treatment of chemotherapy-induced anemia. By 2003 Aranesp had sales of $283 million.

224B. NEUPOGEN® (filgrastim) was approved in 1991. NEUPOGEN® is indicated for decreasing the incidence of infection associated with chemotherapy-induced neutropenia in cancer patients with nonmyeloid malignancies. In 2002, Amgen introduced Neulasta® (pegfilgrastim), a longer-acting form of filgrastim approved for the same use but requiring only one injection per chemotherapy cycle.

231. Since its introduction, Aranesp has been locked into a knock-down competitive battle with Ortho Biotech's Procrit.

225A. A review of their respective websites reveals that Amgen and Ortho are targeting the exact same type of patient with respect to use of Aranesp and Procrit. Amgen describes Aranesp on its website as follows:

> That's where Aranesp® can help. Aranesp® stimulates natural production of red blood cells boosting the number of red blood cells in the body, which can increase the amount of oxygen in your blood and give you more energy. And since you will need fewer shots and doctor visits, you can begin to feel less like a patient and more like a person – and get back to being you again.

> Aranesp® is available by prescription only. Aranesp® has been approved by the Food and Drug Administration to treat the anemia associated with chronic renal failure (renal disease) in people with reduced kidney function or on dialysis. People who have uncontrolled high blood pressure should not use Aranesp®.

225B. Ortho promotes and describes Procrit on its website as follows:

> PROCRIT® (Epoetin alfa) is for the treatment of anemia in patients who have chronic kidney disease and are on dialysis. PROCRIT has a proven safety record. Your doctor should carefully monitor your blood pressure and hemoglobin for rapid increases, which should be avoided. PROCRIT is available by prescription only and is administered by your health care provider.

(Emphasis added).

232. Thus, these two companies were targeting the exact same patients and have an incentive to compete based on the spread that they could offer physicians.

226A. Amgen's Neupogen also competed with Immunex's Leukine prior to Amgen's acquisition of Immunex. Both of these drugs are Part B covered drugs and as set forth below this competitive landscape became a breeding ground for competition based on spread or discounts off AWP. Competition also existed between Amgen's Remicade and Immunex's Embrel, which created a climate for using the spread between AWP and acquisition cost as an inducement to wholesalers and other providers.

2. Amgen's Definition and Understanding of AWP

226B. Internally, Amgen defines AWP as "the common basis for reimbursement by payors. AWP may not necessarily reflect the actual purchase price" (Press Release, "Data from Study Shows Aranesp …," Dec. 9, 2002 (www.amgen.com)) or "one of the factors used by Medicare to determine payment for drug charges."

3. Amgen Controls the Published AWP for Its Products

233. Amgen has controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period.

4. Amgen Understands the Importance of Reimbursement Rates

227A. Amgen was well aware that its customers' profits depended on reimbursement rates for drugs, and that Amgen's own sales and profits in turn depended on its customers' reimbursement payments and profits:

> Our sales depend on payment and reimbursement from third-party payors, and a reduction in the payment rate or reimbursement rate could result in decreased sales of our products.
>
> In both domestic and foreign markets, sales of our products are dependent, in part, on the availability of reimbursement from third-party payors ... ***we believe that sales of Aranesp and Neulasta are and will be affected by government and private payor reimbursement policies.*** ... If reimbursement for our marketed products changes adversely or if we fail to obtain adequate reimbursement for our other current or future products, health care providers may limit how much or under what circumstances they will administer them, which could reduce the use of our products or cause us to reduce the price of our products. This could result in lower product sales or revenues ...

(Amgen 2002 Form 10-K at 43-44).

227B. The foregoing references referring to "reimbursement policies" refers to policies that use AWP as the benchmark for reimbursement.

234. Amgen also made sure its sales representatives were focused on reimbursement and customer profit motives. A senior Amgen sales manager has publicly stated:

> Reps need to understand the insurance system flawlessly. They need to understand the money trail in terms of how a drug gets reimbursed, who reimburses it, and coverage or policy limitations – those are fundamental questions."

228A. Part of that "understanding" was an explanation by Amgen sales representatives that was routinely made by sales representatives to physicians concerning profit that a physician could make by purchasing at a discount off AWP. With respect to, for example, Aranesp and Neupogen, Amgen sales representatives either handed out calculations showing the spread off of AWP that a provider could realize by using Amgen's drugs, or orally reviewed such profits with physicians.

228B. Amgen has also established a website (www.reimbursementconnection.com) to help providers with reimbursement issues, including information on how to calculate reimbursement for Amgen drugs and Sample Reimbursement Sheets detailing how much Medicare will pay for Amgen drugs. In addition, Amgen maintains a telephone Reimbursement Hotline for providers or their office staffs to call to get help with reimbursement questions.

235. Amgen actually promotes the use of AWPs for reimbursement purposes on its website as follows:

Sample of Reimbursement Payments for Aranesp® Syringe/Vial Strengths

		Medicare		
Syringe/Vial Strength	**Average Wholesale Price (AWP)[1/2]**	**85% of Medicare Allowable (AWP)**	**Payment[1] (at 80%)**	**Secondary Insurer or Patient Co-Payment[2] (at 20%)**
J0880 – 25 mcg*	$124.69	$105.99	$84.79	$21.20
J0880 – 40 mcg*	$199.50	$169.58	$135.66	$33.92
J0880 – 60 mcg*	$299.25	$254.36	$203.49	$50.87
J0880 – 100 mcg*	$498.75	$423.94	$339.15	$84.79
J0880 – 150 mcg**	$748.13	$635.91	$508.73	$127.18
J0880 – 200 mcg*	$997.50	$847.88	$678.30	$169.58
J0880 – 300 mcg*	$1,496.25	$1,271.81	$1,017.45	$254.36
J0880 – 500 mcg†	$2,493.80	$2,119.73	$1,695.78	$423.95

[1] As reported in *Drug Topics Red Book®*, February 2004.
[2] Most private insurers base reimbursements for drugs on a percentage above or below published AWP.
* These strengths are available in either Arenesp® SingleJect® prefilled syringes or vials.
† Available only in Aranesp® SingleJect® prefilled syringe.
** These strengths are available in vials only.

229A. In the above table, Amgen recognizes the impact of an AWP-based price on a "secondary insurer" or patient making copay. Amgen thus promotes AWP all the while knowing that the posted AWP is artificially inflated as described.

5. Specific Examples of AWP Abuse

229B. At all relevant times Amgen understood that reimbursement for its drugs was dependent upon AWP. Amgen set the AWPs for its products in an arbitrary manner that rendered AWP to be a fictitious number in that it failed to account for rebates, volume discounts and other incentives provided to physicians and others purchasing Amgen drugs.

236. Both Procrit and Aranesp are Part B covered drugs, hence given the competition between the two, one clear way to increase market share was to increase the spread and hence the profit to providers. Indeed at Aranesp's launch to the oncology market Amgen sales representatives had ready at their fingertips information concerning Aranesp's AWP, the Medicare reimbursement amount, WAC, WAC minus discounts and the "profit" created by the spread between Medicare reimbursement and net acquisition cost.

230A. It was intended by Amgen's top sales executives that its sales force would use this "profit" as a basis for marketing Aranesp.

230B. Examples of the improper use of AWPs by Amgen are set forth below. For example, to increase its market share Amgen in 2003 offered Aranesp to customers with a rebate or discount of up to 30% off of list price, which in itself is 20%-25% off of the published AWP. Thus, Amgen was offering spreads of 50% or more off of the published AWP on Aranesp. These spreads are being offered while Amgen is promoting use of AWP on its own website.

237. On or about July 18, 2003, Amgen extended this discount through July 15, 2004. Thus, even in the face of this litigation, Amgen was offering substantial discounts which rendered the reported AWPs inflated and without basis.

231A. The spread on Aranesp was created at the time of its introduction, and Amgen has published an AWP that created at times at least a 40% spread between the estimated cost to a dispenser and AWP. Given the significant cost of Aranesp this is about $300 per unit for most NDCs. If a typical treatment involves two doses twice a month for a three- to four–month

period, the cost of this spread is $1800 - $2400 per patient. For a Medicare patient this could increase co-payments by $360 - $480.

231B. The use of rebates and off-invoice discounts did not start in 2003 but occurred shortly after Aranesp was introduced in 2002. The allegation is based on (a) the fact that the competition between Amgen and Ortho existed before 2003, (b) that Ortho was heavily engaged in its own conduct directed at marketing the spread and Amgen needed to respond in kind, (c) Amgen was offering "introductory" discounts that inflated AWP, and (d) as noted above Amgen sales representatives were armed with calculations showing the profit created by the Aranesp spread. Ortho, at national sales meetings, authorized its sales and marketing representatives to provide free samples as a means of lowering acquisition costs to providers. Ortho also used inducements such as educational and promotional grants to win over clinics and other providers and as credit memos which were inducements for a clinic or provider to use Procrit exclusively. Amgen sales representatives learned of these efforts and reacted to them by offering inducements of their own. These inducements included rebates based upon volume used by the practitioner.

238. Amgen's efforts at using inflated AWPs to increase market share were successful as Aranesp sales have steadily increased.

232A. Amgen's AWP-related manipulation did not stop at Aranesp. Prior to its acquisition of Immunex, Amgen competed with Immunex with respect to its drug Neupogen and Immunex's Leukine. Documents produced by Immunex reveal that Immunex was marketing Leukine based on the spread, promoting its spread of $80.60 per vial as an advantage over Amgen's $51.61 spread per vial. At the time of this spread marketing by Immunex, Amgen published an AWP for Neupogen of roughly $263.30, and was selling its product to doctors at $201.16. This created a spread of 31% off of AWP which, given the high price of each vial,

would have a substantial impact on co-payors and third-party payors, and provided a handsome profit to providers.

232B. Amgen's use of the spread did not go unnoticed by competitors. In an internal memorandum, employees of a competitor, Centecor, wrote in the context of "reimbursement issues" that doctors have a "fear of audit and not being perceived as infusing only for profit," *i.e.*, using infusion where other treatments were available, but noted that Amgen had no issues in encouraging oncologists to choose drugs based on the spread:

> We need to do a stronger job up front driving home the patient benefit of PMP. One of the other reasons I see doctors hitting a point and not moving forward is fear of audit and not being perceived locally as infusing only for profit. An example of what goes on in other specialties might be of benefit -- personally I would use an ***Amgen*** or Immunex oncology product and show the AWP versus payment. [redacted] We don't need to make this a big production–if you put the slide up with the product and company the attendees can connect the dots.

239. The foregoing e-mail is in effect competitor intelligence confirming that Amgen was marketing the spread on its products sold to oncologists, which include Aranesp, Neulasta and Neupogen.

233A. Spreads created for Neupogen are set forth below for a 300ml dose. Not only are the spreads sizable, but reported AWPs increased faster than the real AWP, thus making the reported AWPs in later years even more inflated. This increase in spread is the direct result of an effort to induce physicians to use Neupogen due to the increase in the spread:

Year	Reported AWP	Real AWP	Spread in Dollars	Percentage
1997	$161.30	$125.09	$36.21	28
1998	$165.30	$130.02	$35.28	27
1999	$180.40	$134.81	$45.91	34
2000	$188.50	$140.49	$39.88	28
2001	$197.80	$148.62	$49.18	33
2002	$207.50	$149.60	$57.90	38

233B. Spreads for the 10,000 u/ml ten pack for Epogen were historically approximately 33%, but beginning in January 2000 Amgen implemented a series of AWP increases so that by 2002 the spread increased to 42%. The increase in spread was designed to increase market share.

240. AWPs for the 4,000 units/ml of Epogen were also inflated with spreads between 92% and 105%. AWPs for this drug/dose increased while costs to the provider decreased. Similarly, the ten pack 4,000 units/ml dose started in 1997 with a spread of 26% that increased to 47% over time.

234A. Amgen has also caused artificially inflated AWPs to be published for its top-selling drug Enbrel. Originally, the spread between AWP and acquisition cost was 25%. This spread has steadily increased over time such that for some doses, the spread is 32% to 40%. Amgen has created this spread to encourage promotion and use of Enbrel by those in the distribution chain.

6. Amgen Rebates on Epogen

2334B. In addition to marketing the spread, Amgen has utilized other impermissible inducements to stimulate sales of its drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price.

241. A 1993 OIG Report detailed how Amgen gave substantial year-end rebates to its customers based on their purchases of Epogen. The report noted that Medicare and Medicare beneficiaries did not receive the benefit of any rebates; all monies remained with the provider. There was no way to provide for any rebates on Medicare claim forms, and Amgen's rebates were not provided until year-end:

> [T]he effect of the rebates is that it reduces the actual cost of EPO to a dialysis facility, thus increasing their gross profit. Presently, the rebates represent price reductions which benefit the facilities exclusively.

("Review of Epogen Reimbursement," (OIG A-01-02-00506 at 7-8)).

235A. By utilizing hidden inducements, Amgen provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.

242. Amgen's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs and its use of hidden rebates and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class.

7. Amgen Concealed Its AWP Manipulation

236A. Amgen deliberately acted to conceal its fraudulent reporting and marketing of the AWP spread. For example, as noted above, Amgen gave rebates to its Epogen customers which effectively lowered the true price charged. When OIG asked Amgen for data on its total sales or the total amount of Epogen rebates, Amgen refused to provide such data. ("Review of Epogen Reimbursement," (OIG A-01-02-00506 at 7-8)).

243. In September 2001, the GAO reported that epoetin alfa accounted for the second highest percentage of Medicare expenditures on drugs in 1999, accounting for 9.5% of spending for prescription drugs by Medicare in 1999 and for 3.4% of all Medicare allowed services.

237A. As set forth above, Amgen's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

C. AstraZeneca

244. AstraZeneca has engaged in an ongoing deliberate scheme to inflate AWPs. The drugs at issue for this defendant are identified in Appendix A and summarized below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
ASTRAZENECA	Accolate	zafirlukast	Leukotriene Antagonist (Respiratory Agent) Used in the treatment of asthma
	Armidex	anastrozole	Antiestrogen (Antineoplastic; Hormonal Agonist/Antagonist) Used in the treatment of breast cancer in postmenopausal women

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Atacand	candesartan cilexetil	Angiotension II Receptor Antagonist (Cardiovascular Agent) Used in the treatment of hypertension
	Atacand HCT	candesartan cilexetil-hydrocholorothiazide	Angiotension II Receptor Antagonist With Diuretic (Cardiovascular Agent) Used in the treatment of hypertension
	Casodex	bicalutamide	Antineoplastic Used in the treatment of prostate cancer
	Diprivan	propofol	General Anesthetic Used in the induction or maintenance of anesthesia as part of balanced anesthetic technique
	Entocort	budesonide	Glucocorticoid Used in the treatment of Crohn's disease
	Nexium	esomeprazole magnesium	Proton Pump Inhibitor (Gastrointestinal Agent) Used in the treatment of heartburn and erosive esophagitis
	Nolvadex	tamoxifen citrate	Antiestrogen (Antineoplastic: Hormonal Agonist/Antagonist) Used in the treatment or prevention of breast cancer
	Prilosec	omeprazole	Proton Pump Inhibitor (Gastrointestinal Agent) Used in the treatment of gastric and duodenal ulcers, gastroesophageal reflux disease and erosive esophagitis
	Pulmicort	budesonide (inh)	Glucocorticoid Used for maintenance treatment of asthma
	Rhinocort	budesonide (nasal)	Glucocorticoid Used in the treatment of allergic rhinitis
	Seroquel	quetiapine fumarate	Antipsychotic Agent (Psychotherapeutic Agent) Used in the treatment of schizophrenia
	Toprol	metoprolol succinate	Beta Adrenergic Blocking Agent (Cardiovascular Agent) Used in the treatment of hypertension, angina pectoris and heart failure
	Zestril	lisinopril	Angiotension Converting Enzyme Inhibitor (Cardiovascular Agent) Used in the treatment of hypertension and heart failure

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Zoladex	goserelin acetate	Gonadotropin Releasing Hormone Analogue (Antineoplastic: Hormonal Agonist/Antagonist) Used in the treatment of prostate and advanced breast cancer
	Zomig	zolmitriptan	Serotonin Receptor Agonist (Migraine Preparation) Used in the treatment of migraines

1. AstraZeneca Has Been the Target of a Government Investigation

245. In connection with its scheme to inflate AWPs, AstraZeneca has been investigated by the United States Department of Justice. In January 2002, a federal grand jury in Wilmington, Delaware returned an indictment accusing a New Jersey doctor of conspiring with AstraZeneca to resell free samples of Zoladex® that AstraZeneca sales representatives had given the doctor. The indictment alleges that AstraZeneca (i) sold Zoladex® to the New Jersey doctor and others at prices substantially below the AWP reported by AstraZeneca, and (ii) provided the New Jersey doctor with materials showing how much more profit he could make by using Zoladex® instead of its competitor, Lupron®.

246. In response to the government's subpoena, AstraZeneca appears to have produced documents related to Zoladex only.

2. AstraZeneca's Definition and Understanding of AWP

247. In AstraZeneca's Guide to Coverage and Reimbursement, AstraZeneca defines AWP as follows:

> Average Wholesale Price (AWP): The composite wholesale price charged on a specific commodity that is assigned by the drug manufacturer and is listed in either the Red Book or Blue Book. AWP is often used by third-party payers as a basis for reimbursement.

(AZ0052597) (Confidential). Thus, by its own definition, AstraZeneca recognizes that: (i) AWP should be an average of actual wholesale prices; (ii) the drug manufacturers control the published AWP; and (iii) the published AWPs directly affect the payments made by the Class.

3. AstraZeneca Controls the Published AWP for Its Products

248. AstraZeneca has controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period. In one internal marketing memorandum, AstraZeneca recommended:

> We take a price increase in December 1995. By doing this, we can inform the Red Book of this increase and it will go into the Red Book for January 1996. This is critical, so that the state Medicare carriers can recognize our new price in January. Typically, the state carriers use the January Red Book and the July Red Book for their reimbursement price of Medicare reimbursed products. Last year when we took the price increase in February there were some Medicare carriers who did not change their reimbursement price until September. Also TAP notifies Red Book 1 month before the price change. We are at a competitive disadvantage with our audience.

(AZ0021838) (Highly Confidential).

4. AstraZeneca's AWP Manipulation Benefited Providers at the Expense of the Class

249. The purpose of AstraZeneca's manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries at the expense of Plaintiffs and the Class.

a. In one internal marketing memorandum, AstraZeneca recognized the profits to providers from the inflation of AWPs: "The market we are in wants a more expensive Zoladex, because the doctor can make more money." (AZ0021838) (Highly Confidential).

b. Similarly, in its agreements with PBMs, AstraZeneca guaranteed that it would maintain a spread between AWP and AWC (average wholesale cost) in order to ensure a profit to PBMs at the expense of the Class. (AZ0036207) (Highly Confidential). For example, in its agreement with Caremark, AstraZeneca stated:

> ZENECA WILL REIMBURSE CAREMARK FOR THE DIFFERENCE BETWEEN THE AMOUNT COLLECTED BY CAREMARK ON EACH PATIENT UNIT SOLD AND AWP AT THE TIME THE UNIT WAS DISPENSED. CAREMARK WILL HAVE EXERCISED BEST EFFORTS TO COLLECT THE

> FULL AWP FROM THE 3RD PARTY PAYER AND THE PATIENT PRIOR TO SUBMISSION TO ZENECA.

(AZ0036208) (Highly Confidential).

c. AstraZeneca recognized that its practices were at the expense of the Class:

> BECAUSE OF OUR STEEP DISCOUNTING, NEARLY HALF THE PROFIT TO BE REALIZED WITH ZOLADEX IS PAID BY MEDICARE. AND SINCE MEDICARE IS THE QUICKEST AND MOST DEPENDABLE PAYOR, THIS WAS SEEN AS AN ENORMOUS BENEFIT. THE OTHER HALF OF THE PROFIT WAS FROM THE PATIENT CO PAY OR SECONDARY INSURANCE . . . .

(AZ0037011) (Highly Confidential).

5. AstraZeneca Manipulated and Marketed the AWP for Zoladex

250. AstraZeneca stated an inflated AWP for Zoladex and marketed the resulting spread during the Class Period. AstraZeneca's documents reveal an intense competition with TAP Pharmaceuticals and its drug Lupron, focusing primarily on the spreads available to physicians between Zoladex and Lupron.

251. For instance, one internal chart touts the greater spread that can be reaped from the inflated AWP for Zoladex over the AWP for Lupron:

	AWP	AWP minus 5%	Current Cost (1 depot)	Return to Practice 1 depot	Current Max Discount 29.5% vs 50%	Return to Practice at Max.
Lupron 3-month depot	$1,622.68	$1,541.55	$1,297.50	$244.05	$915.00	$626.55
Zoladex 3-month depot	$1,231.53	$1,169.95	$985.22	$184.73	$492.61	$677.34

(AZ 0055816) (Highly Confidential).

252. Another document announcing new pricing for Zoladex states:

> With a purchase of 72+ depots of ZOLADEX and the additional 2% for paying within 30 days yields the doctor a $133.67 profit margin with ZOLADEX vs $133.50 with a purchase of 101+ depots of Lupron. For those offices that purchase between 60-100 depots of Lupron monthly, they can increase their profit margin greatly by purchasing ZOLADEX.

(AZ 0037019) (Highly Confidential).

253. Moreover, AstraZeneca repeatedly tried to educate providers regarding the Medicare reimbursement system and the benefits to the providers for Zoladex utilization. For example in a document sent to providers AstraZeneca states:

The following is a cost comparison of Zoladex® vs Lupron® 7.5 mg where Zoladex® is purchased under the buying power of the Urology Purchasing Group, St. Louis, Mo. The calculations reflect prices/discounts effective as of 2/1/94.

	ZOLADEX	LUPRON			
Quantity	1	1-11	12-25	26-50	Your Office
Direct Drug Cost	$345.97	$371.00	$360.99	$352.50	$
Medicare $ Claim Medicare Payment to MD	$344.76 x 80.5% $275.81	$463.75 x 80% $371.00	$463.75 x 80% $371.00	$463.75 x 80% $371.00	$463.75 x 80% $371.00
Patient / 3rd Party Payment*	$344.76 -275.81 $ 68.95	$463.75 -371.00 $ 92.75	$463.75 -371.00 $ 92.75	$463.75 -371.00 $ 92.75	$463.75 -371.00 $ 92.75
Medicare Claim Direct Drug Cost Total Profit Per Injection	$344.76 -345.97 $ 98.79	$463.75 -371.00 $ 92.75	$463.75 -360.00 $103.75	$463.75 -352.50 $111.25	$463.75 -_____
Difference		$ 6.04	$ 4.96	$ 12.46	$_____
Percent Profit per Injection	40%	25%	29%	32%	__%
Additional Cost outlay of Lupron vs Zoladex (Direct Cost vs Direct Cost)		$125.03	$114.03	$106.53	$_____

ILLUSTRATION: If your office uses between 12 and 25 Lupron® units per month, your total "profit" per injection, over Zoladex, is $4.96 but your additional outlay per Lupron injection is $114.03. This represents and unnecessary tie up of corporation monies. Based on 12 Lupron injections per month, your office has "tied up" $1,368.36 to achieve a "profit" of $59.52. In this example, Zoladex represents a 40% return on investment vs. 29% for Lupron.

* Calculations assume a 100% collection of monies from patient or 3rd party. If Lupron® is used instead of Zoladex® and the 20% is not collected, then the office has lost $23.80 per injection ($92.75 - $68.95 = $23.80).

01-25-0418

(AZ0046085) (Highly Confidential).

254. Internal AstraZeneca documents reveal that AstraZeneca was directly marketing the spread to physicians. A memo announcing price changes for Zoladex states:

> We have raised AWP and AWC by 7% and have increased our discount level higher at all purchasing tiers.
>
> Pricing on Zoladex 3-month is as follows:

Discount		AWP	Cost
1-5 depots	0	1206.49	966.79
6-11 depots	11	1206.49	860.44
12-23 depots	15	1206.49	821.77
24-47 depots	17	1206.49	802.44
48-59 depots	20	1206.49	773.43
60-71 depots	22	1206.49	754.10
72-96 depots	24	1206.49	734.76
96-191 depots	25	1206.49	725.09
192 +	30	1206.49	676.75

> Zoladex AWP has been priced at a 5% premium above 3 times the Zoladex 1-month depot. The discount levels have been increased also.

(AZ 0024566-67.)

255. Thus, at the same time AstraZeneca was raising the AWP for Zoladex, it was lowering the real price to providers (by giving bigger discounts), which served to widen the spread.

256. Another document sets forth the difference between the purchase price and the AWP at various volume levels. Note that even with no volume discount, a provider is still making at least a $71.00 profit per unit on Zoladex ($358.55 - 286.84 = 71.71):

> NEW LOWER CASE QUANTITY DISCOUNT
> ZOLADEX PRICING

UNITS	AWP	COST	DISCOUNT	LESS 2%
1-5	$358.55	$286.84	0%	$281.10
6-11	$358.55	$269.63	6%	$264.24
12-23	$358.55	$261.02	9%	$255.80
24-47	$358.55	$252.42	12%	$247.37
48-59	$358.55	$243.81	15%	$238.93
60-71	$358.55	$235.21	18%	$230.50
72+	$358.55	$229.47	20%	$224.88

(P003060.)

257. The same document goes on to tout the practice's ability to make more profit, or return on investment, by exploiting the AWP scheme:

> Thank you for your time and listening ear on Monday, April 17. As discussed, I am offering a proposal to switch Lupron patients to Zoladex. Zeneca Pharmaceuticals now has new volume pricing, with a 20% maximum discount, for Zoladex. What this will offer the practice is an opportunity to save money, realize a better return on investment, achieve the same profit you currently have with our competitor and free up a substantial amount of working capital. Zoladex will also save the patient money and the system money.
>
> Based on a comparison of Zoladex and Lupron, if 480 depots are used annually Zoladex will save the practice $57,177.60 a year. Your dollar return to the practice is now slightly higher with Zoladex. This rate of return for Zoladex is now 59% compared to Lupron's 39%

(P003058.)

258. Another AstraZeneca document even more explicitly demonstrates to providers how they can profit from the AWP scheme, in excess of $64,000 per year:

ZOLADEX

Direct Pricing	Medicare AWP	$$Return / % Return
72+ $224.88	$358.55	$133.67 59%
72x$224.88=$16,191.38	72x$358.55=$25,815.60	$9,624.24 59%
based on your use of 480 depots annually, with our 2% discount these are the comparisons		
$107,942.40	$172,104.00	$64,161.60 59%

(P003058.)

259. According to a September 2001 GAO report, the discount from AWP for medical providers who purchased AstraZeneca's Zoladex and billed Medicare was between 21.9% and 22.3%. ("Payments for Covered Outpatient Drugs Exceed Providers' Cost, Sept. 2001" (P005546-78).)

260. AstraZeneca, through its employees and agents, also provided millions of dollars worth of free samples of its drugs to providers. The free samples would be used to offset the total cost associated with purchases of its drugs, thereby increasing the spread, while also concealing the actual cost of the drug from Plaintiffs and the Class. Moreover, at least as to Zoladex®, AstraZeneca sales representatives specifically told providers that they could and should bill for the free samples.

261. A written proposal from AstraZeneca Sales representative Randy Payne dated July 17, 1995 encourages a urology practice to switch all of their patients to Zoladex and states: "AS AN ADDED INCENTIVE, ZENECA WILL PROVIDE YOU WITH 50 FREE DEPOTS (over $11,900 worth of product) FOR THE INITIAL CONVERSION TO ZOLADEX." (P003059.)

262. As set forth above, AstraZeneca's scheme to inflate its reported AWPs for Zoladex, market the resulting spread, and channel to providers "free" goods – all in order to increase the market share of its drugs – has resulted in excessive overpayments by Plaintiffs and the Class.

D. The Aventis Group (Aventis, Pharma, Hoechst and Behring)

263. Aventis engages in an organization-wide and deliberate scheme to inflate AWPs. Aventis has stated fraudulent AWPs for all or almost all of its drugs, including those set forth below. The specific drugs of Aventis for which relief is sought in this case are set forth in Appendix A or in the proposed class certification order, and are summarized below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
AVENTIS GROUP (Aventis, Pharma, Hoechst and Behring)	Allegra	fexofenadine	Antihistamine Used for the relief of symptoms of seasonal allergic rhinitis
	Allegra-D	fexofenadine pseudoephedrine	Antihistamine Used for the relief of symptoms of seasonal allergic rhinitis

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Amaryl	glimepiride	Antidiabetic Used to lower blood glucose in Type II diabetes patients
	Anzemet	dolasetron mesylate	Antineoplastic Used to prevent nausea and vomiting after chemotherapy or operation
	Arava	leflunomide	Antirheumatic Used in the treatment of active rheumatoid arthritis
	Azmacort	triamcinolone aceonide (inh)	Steroidal Anti-Inflammatory Agent (Respiratory Agent) Used for maintenance treatment of asthma
	Calcimar	calcitonin salmon	Parathyroid Agent Used in the treatment of blood calcium levels and to increase the level of calcium in the bones
	Carafate	sucralfate	Duodenal Ulcer Adherent Complex (Gastrointestinal Agent) Used in the treatment and maintenance therapy of duodenal ulcer
	Cardizem	diltiazem	Calcium Channel Blocker (Cardiovascular Agent) Used in the treatment of angina and hypertension
	Gammar PI.V.	immune globulin	Immunizing Agent Used as a maintenance therapy in patients with compromised immune systems
	Intal	cromolyn sodium	Antiasthmatic Used to treat allergic rhinitis and severe perennial bronchial asthma
	Nasacort	triamcinolone acetonide (nasal)	Steriodal Anti-Inflammatory Agent (Nasal Preparation) Used for nasal treatment of allergic rhinitis symptoms
	Taxotere	docetaxel	Antineoplastic Used in the treatment of breast or lung cancer after failed chemotherapy
	Trental	pentoxifylline	Blood Viscosity-Reducing Agent (Blood Modifier) Used to improve the flow of blood through blood vessels

1. Aventis Has Been the Target of Government Investigations

264. In connection with its scheme to inflate AWPs, Aventis has been investigated by the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services, the Commerce Committee of the U.S. House of Representatives, the Attorney General for the State of Texas, the Attorney General for the State of California, and the State of California Department of Justice Bureau of Medi-Cal Fraud and Elder Abuse.

2. Aventis' Definition and Understanding of AWP

265. Internal documents recently produced by Aventis reveal the definition of AWP used and understood by Aventis and its predecessor companies. Specifically, a November 1992 internal newsletter at Armour Pharmaceutical Company (a predecessor company to Centeon LLC, later known as Aventis Behring) states:

> "AWP" is common language among insurance carriers (state, federal and private). The acronym stands for Average Wholesale Price. AWPs are set by manufacturers as a "suggested retail" for the products they produce. ***These figures represent a reasonable profit margin to healthcare providers and as such are widely referenced by insurance carriers when setting reasonable and customary rates of reimbursement.***
>
> Average Wholesale Prices are printed in Red Book Drug Topics and Blue Book. Both serve as data resources to all state Medicaid programs. Each publication lists the drugs by brand name in alphabetical order with its corresponding descriptions.

(ABAWP 008990-91) (Highly Confidential) (emphasis added).

266. Aventis possessed the *Red Book*'s definition of Average Wholesale Price:

> Average wholesale price (AWP) is the standardized cost of a drug, which managed care plans frequently use for determining drug benefits. The AWP is determined through reference to a common source of price information, such as the American Druggist's *Blue Book*, which lists the costs charged for an undiscounted drug to a pharmacy by a large group of pharmaceutical wholesale suppliers. AWP's are set by pharmaceutical manufacturers and supplied to all pricing data banks for publication.

(ABAWP 012067) (Highly Confidential).

3. Aventis Controls the Published AWP for Its Products

267. Aventis controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period.

a. For example, on December 29, 1997, Rhone-Poulenc Rorer (a subsidiary of Rhone Poulenc SA, which merged with Hoechst AG to form Aventis in 1999) submitted a list of AWP price increases effective January 1, 1998 to both Medi-Span and First Data Bank. Aventis instructed Medi-Span and First Data Bank to "change [their] records accordingly to reflect the new prices." (AV-AAA-001054) (Confidential). Similar letters requesting price changes for 1999 were sent to Medi-Span and First Data Bank by Aventis on December 29, 1998. (AV-AAA-001047) (Highly Confidential), (AV-AAA-001050) (Highly Confidential), and price changes for 1997 on December 23, 1996 (AV-AAA-001066) (Highly Confidential).

b. An April 1, 1998 letter from Centeon notifies Medical Economics (the *Red Book*) that effective April 1, 1998, it "has raised AWP pricing" for Bioclate and Monoclate. (ABAWP 005314) (Highly Confidential).

4. Aventis' AWP Manipulation Benefited Providers at the Expense of the Class

268. The purpose of Aventis' manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries at the expense of Plaintiffs and the Class.

269. Aventis knew that AWP manipulation, and the related marketing of an AWP spread, was improper. An internal Aventis (Centeon) document, in pertinent part, states – in large, bold print:

> **ATTENTION!**
>
> SELLING AGAINST AWP
>
> This is <u>not</u> an option.
>
> Traditionally, some manufacturers have promoted differences in AWPs as a means to sell their products. Centeon does not do this,

> and we hope to hear from you if you learn that any other manufacturer (sic) are using this tactic.
>
> Some pharmaceutical manufacturers set high AWPs as a means of securing market shares for their drugs. Although not illegal, the intensity of government scrutiny of this and other pharmaceutical manufacturer pricing practices is increasing. The inspector general is looking at prices for big-ticket drugs
>
> ***
>
> At the risk of being redundant it is imperative to stress that AWP can not (sic) be used in the content of selling any of our products. If you are made aware, either orally or through written correspondence, of anly manufacturer using this form of sales tactic immediately report such findings to Gene Hull and appropriate steps will be taken.

(ABAWP 000855) (Highly Confidential).

270. Nonetheless, Aventis (Centeon) routinely promoted differences in AWPs in marketing its numerous products. In seminar materials used in conjunction with an "Oncology University Anzemet Workshop" held in 1998, Aventis explained to attendees how its AWP spread could be exploited. Aventis offered the following definition and example of AWP spread:

> **SPREAD**
>
> - Difference between acquisition cost (AC) and reimbursement (Profit, Margin, etc.).
> - Example for Anzemet
>
> -AC = $68 for 100 mg vial
> -AWP = $166.50
> -AWP – 5% = $158.18
> -80/20 = $126.54/$31.64
> -Spread = $58.54 + $31.64 = $90.18

(AV-AAA-02242-56) (Highly Confidential).

271. Aventis, through its employees and agents, also provided free samples of its drugs to providers. (ABAWP 000089) (Highly Confidential) (ABAWP 000811) (Highly Confidential). The free samples would be used to offset the total cost associated with purchases of its drugs,

thereby increasing the spread, while also concealing the actual cost of the drug from Plaintiffs and the Class. In fact, a 1995 "SALES AND FREE GOODS STATUS" memo reveals that Aventis (Armour) issued millions of "free goods units" to a single customer alone. (ABAWP 000220-25) (Highly Confidential).

272. Further, just as Aventis motivates providers to administer drugs based on the AWP, Aventis rewards PBMs based on the degree of influence they exert to drive utilization of Aventis products. (AV-AAA-000197-99) (Highly Confidential).

5. Specific Aventis AWPs Documented by the DOJ

273. In a report published by the DHHS (AB-00-86), the DOJ documented at least 15 instances where the published AWPs for various dosages of 4 drugs manufactured by Aventis were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the 4 drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Aventis in the 2001 *Red Book*.

Drug	2001 *Red Book* AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Anzemet Injectable (dolasetron mesylate)	$166.50	$74.08	$92.42	125%
Factor VIII/ Bioclate	$1.25	$.91	$.34	37%
Factor VIII/ Helixate	$1.18	$.78	$.40	51%
Gammar (immune globulin)	$400.00	$296.67	$103.33	35%

(P006299-P006316).

274. An OIG report (*see* "Medicare Reimbursement of Prescription Drugs," OEI-03-00-00310, Jan. 2001) further revealed that: (i) the AWP for all immune globulin 5 mg doses listed in the 1997 *Red Book* were inflated by an average spread of 32.21%; (ii) a 10 mg dose of Anzemet had a Medicare Median of $14.82 and a Catalog Median of $8.29, resulting in a spread

of 78.76%; and (iii) a 20 mg dose of Taxotere had a Medicare Median of $283.65 and a Catalog Median of $8.29, resulting in a spread of 18.75%. (P006398-006424).

6. Additional Evidence Concerning Anzemet

275. Aventis distributed a "Reimbursement Spreadsheet" to be utilized by its sales personnel to demonstrate to "private practice office" customers the "financial advantages" of its drug, Anzemet, compared to Zofran and Kytril based on Aventis' established AWP and acquisition price (total reimbursement through Medicare). (AV-AAA-001190-93) (Highly Confidential). Aventis also communicated to its sales staff on December 7, 1998 that "Anzemet still [held] the advantage on spread" following a Kytril price increase. (AV-AAA-002291) (Highly Confidential).

276. Another Aventis internal document also addresses how a particular Aventis customer might increase its margin choosing Anzemet over the competition:

> Cost and Reimbursement: OnCare has negotiated a very favorable contract with Hoechst Marion Roussel [an Aventis predecessor company], manufacturer of Anzemet. Our cost from OTN for the Anzemet 100 mg/ml vial is reduced from approximately $70 ea. to $62.50. In addition there will be quarterly rebates further reducing the cost to $61.25. The AWP is $149.88, making the margin $88.63. Additional returns can be realized by using 1.8 mg/kg as recommended in the package insert. For example, for a patient weighing 70Kg, the dose is 126 mg, requiring 2 vials. Since the vial is single use, you may bill for both vials: total cost is $122.50, the AWP is $299.76, the net is $177.26 (assuming reimbursement at AWP). By comparison the current margin for 0.7 of Kytril is $54.89. For 1 mg it is $78.42. If there is a price increase in 1999 (which we expect) our prices are protected, however the AWP will go up, further increasing the margin. The contract makes Anzemet the preferred 5-HT3 antiemetic drug for OnCare.

(AV-AAA-001523) (Highly Confidential). Other customers received promotional materials reflecting a significant spread between the unit price and AWP for Anzemet – and touting a "Reimbursement and Patient Assistance Program Hotline." (AV-AAA-001619-23) (Confidential).

277. A government investigation revealed similar inflated pricing implemented by Aventis with respect to the injectable form of Anzemet. In a September 28, 2000 letter to Alan F. Holmer, President of the Pharmaceutical Research and Manufacturers of America, U.S. Rep. Pete Stark provided a synopsis of the scheme implemented by Aventis (Hoechst):

> The following chart represents a comparison of Hoechst's fraudulent price representations for its injectable form of the drug versus the truthful prices paid by the industry insider. It is [sic] also compares Hoechst's price representations for the tablet form of Anzemet and the insider's true prices. It is extremely interesting that Hoechst did not create a spread for its tablet form of Anzemet but only the injectable form. This is because Medicare reimburses Doctors for the injectable form of this drug and by giving them a profit, can influence prescribing. The tablet form is dispensed by pharmacists, who accept the Doctor's order. And this underscores the frustration that federal and state regulators have experienced in their attempts to estimate the truthful prices being paid by providers in the marketplace for prescription drugs and underscores the fact that, if we cannot rely upon the drug companies to make honest and truthful representations of their prices, Congress will be left with no alternative other than to legislate price controls.

NDC No:	Unit Size/ Type	Quantity	Net Price as Represented to Florida Medicaid	True Wholesale Price	Variance
0088-1206-32	100 mg/5 ml Injectable	1	$124.90	$70.00	Represented price 78% higher than true wholesale price.

(P007548-007588).

7. Additional Evidence Concerning Gammar

278. Similarly, Aventis increased AWPs for its Gammar product line to keep provider and intermediary reimbursement levels competitive with those created by the inflated AWPs of other manufacturers. A May 8, 1996 Aventis (Centeon) Interoffice Correspondence memo states:

> Effective June 1, 1996, we will be revising our AVERAGE WHOLESALE PRICE for our Gammar P iv product line. We are implementing this change based on feedback from the field. Alpha and Bayer have recently increased their AWP pricing on

> Gammimmune 10% and Venoglobulin S 10%. They are presently priced at $75 and $80 per gram respectively. . . . This change will help us maintain a competitive balance in the marketplace.

(ABAWP 004767) (Highly Confidential).

279. Centeon interoffice correspondence, dated June 23, 1999, reveals that a Centeon employee provided a representative of First Data Bank with the following information regarding Centeon's AWP for Gammar:

> She asked me to validate Centeon's AWP and wholesale list price for Gammar PIV 5 and 10 gram vials.
>
> ***
>
> I gave her the following info:
>
> "Currently it is not Centeon's business practice to sell Gammar PIV to wholesalers. But should a wholesaler place an order, our wholesale list price is $52/gram, or $260 for 5 gram vial, and $520 for 10 gram vial."
>
> "Centeon's suggested AWP is $400 for 5 gram vial, and $800 for 10 gram vial. This is pricing as reported to First Data Bank, but we do not sell product at these prices."

(ABAWP 005315) (Highly Confidential).

280. U.S. Rep. Thomas J. Bliley, in a May 4, 2000 letter to the CEO of Aventis (Behring), also stated concerns regarding Aventis' pricing of Gammar:

> The Office of Inspector General (OIG) at the Department of Health and Human Services determined that the Medicare-allowed amount for immune globulin, a pharmaceutical product sold by your company under the name Gammar, in Fiscal Year 1996 was $42.21. The OIG further estimated that the actual wholesale price of this drug was $16.12 and the highest available wholesale price that the OIG was able to identify was $32.11.

(P006962-P006966).

8. Inflated AWPs From Aventis' Price Lists

281. In response to government subpoenas, Aventis produced numerous price lists setting forth spreads between AWPs and prices offered to wholesalers, providers and other

intermediaries. A review of those price lists reveals that Aventis has consistently offered drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers. To repeat every one of those drugs and the spread offered to each specific customer here is not practical.

282. A March 4, 1997 price list issued by Arcola Laboratories (a division of Rhonel-Poulenc Rorer Pharmaceuticals sets the AWP for Calcimar (calcitonin-salmon) at $31.35, with a cost of $12.00 – for a spread of 161%. (AV-AAA-000705).

283. As set forth above, Aventis' scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

9. Aventis Concealed its AWP Manipulation

284. Aventis deliberately acted to conceal its fraudulent reporting and marketing of the AWP spread. For example, in response to a May 26, 1995 fax request from *Red Book*, Aventis refused to provide Wholesale Acquisition Cost (WAC) for products it listed in the *Red Book* database – in spite of *Red Book's* assurances that WAC information would be distributed via electronic means only. (ABAWP 008420) (Highly Confidential). Aventis effectively hid the AWP spread from Plaintiffs and the Class.

E. Baxter

285. Baxter engages in an organization-wide and deliberate scheme to inflate AWPs. Baxter has stated fraudulent AWPs for all or almost all of its drugs those set forth below. The specific drugs of Baxter for which relief is sought in this case are set forth in Appendix A or in the proposed class certification order, and are summarized below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
BAXTER	Aggrastat	tirofiban hydrochloride	Glycoprotein Receptor Inhibitor (Blood Modifier) Used in the treatment of acute coronary symptoms
	Ativan	lorazepam	Antianxiety Agent (Psychotherapeutic Agent); Anticonvulsant Used to relieve anxiety and treat insomnia
	Bebulin VH	factor ix (systemic)	Antihemorrhagic Agent Used to treat hemophilia B
	Brevibloc	esmolol hcl	Autonomic Nervous System Agent Used in the treatment of tachyarrhythmias in critical situations
	Buminate	albumin (human)	Plasma Fraction (Blood Modifier) Used in the treatment of hypovolemia and hypoalbuminemia
	Claforan	cephalosporin (systemic)	Antibacterial Agent (Anti-Infective Agent) Used in the treatment of infections caused by bacteria
	Gammagard S/D	immune globulin solution	Antibacterial Agent (Anti-Infective Agent) Used to prevent or treat some illnesses.
	Gentran	dextran	Blood Derivative; Blood Modifier Used in the emergency treatment of shock
	Holoxan/Ifex	ifosfamide	Antineoplastic Used in the treatment of various forms of cancer
	Iveegam EN	immune globulin iv	Antibacterial Agent (Anti-Infective Agent) Used as replacement therapy in patients with primary immunodeficiency syndromes
	Osmitrol	mannitol	Osmotic Diuretic Used to promote diureses during treatment of acute kidney failure. Also used to reduce intraocular and intracranial pressure
	Recombinate	factor viii	Antihemophilic Factor Used to induce blood clotting
	Travasol	amino acid	Dietary Supplement Used for nutritional support in cancer patients
	Vancocin HCl	vancomycin hydrochloride	Antibacterial Agent (Anti-Infective Agent) Used in the treatment of infections caused by bacteria
		cisplatin	Antineoplastic Used to treat cancer of the bladder, ovaries, and testicles
		dextrose	Caloric Agent; Electrolyte Replenisher Used to increase intake of calories and fluids

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
		doxorubicin hcl	Antineoplastic Used in the treatment of various forms of cancer
		gentamicin	Antibacterial Agent (Anti-Infective Agent) Used to treat serious bacterial infections
		heparin	Anticoagulant (Cardiovascular Agent) Used to decrease the clotting ability of the blood
		sodium chloride	Flush; Abortifacient Used to remove medicine and blockage from intravenous (IV) catheter. Also used to induce abortion

1. Baxter Has Been the Target of Government Investigations

286. Baxter has been investigated by the United States Department of Justice, Department of Health and Human Services Office of Inspector General, the Attorney General for the State of California, the Attorney General for the State of Texas, the Attorney General for the State of Illinois, and the Committee on Commerce of the House of Representatives.

287. These investigations confirm that Baxter has engaged in a deliberate scheme to inflate AWPs for many or most of its drugs. A Baxter document made public as a result of the congressional investigation entitled, "Confidential – Baxter Internal Use Only," acknowledged that: "Increasing AWPs was a large part of our negotiations with the large homecare companies." Baxter further admitted in internal documents that homecare companies that reimburse based on AWP make a significantly higher margin. Thus, Baxter's own documents demonstrate its active participation in the scheme to artificially inflate AWPs.

2. Baxter's Definition and Understanding of AWP

288. Despite its manipulation, Baxter understood what AWP should mean: "The average price that a pharmacy (or provider) pays for the product from their drug wholesaler or distributor." (BAX MDL 0011378) (Highly Confidential). Contrary to its own definition of

AWP, Baxter nonetheless set AWPs for its drugs far in excess of what providers paid for those drugs.

3. Baxter Controls the Published AWP for its Products

289. Baxter has controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period. For example, a September 7, 1995 inter-office memorandum provides:

> I have been in contact with both *Red Book* and Medispan earlier this year about our AWPs. I told them that we will not be raising our AWPs for FVIII in 1995, and will only increase IGIV in the event of a label change. There are a few general rules about AWP adjustments.
>
> • A manufacturer may raise AWPs at any time in the year. There is a monthly publication called the *Red Book* Update that lists all changes to the April publication (the big red book).
>
> • If a manufacturer does decide to increase AWPs: - payors want a justification for the increase. This is why we typically don't increase the AWP unless we have a label change, product enhancement . . . .

(BAX MDL 0004754) (Highly Confidential).

4. Baxter's AWP Manipulation Benefited Providers at the Expense of the Class

290. In at least one internal document, Baxter recognized that deliberate manipulation of the spread was being wrongly used to gain competitive advantage by manufacturers:

> ***The deliberate manipulation of AWP or WAC prices is a problem that we need to address. The spread between acquisition cost and AWP/WAC is direct profit for customers, and is being used to increase product positioning in the market by certain manufacturers.***

(BAX MDL 0012778) (Highly Confidential) (emphasis added).

291. Despite this recognition, Baxter nonetheless continued to manipulate its AWPs in order to maintain the competitiveness of its own products based upon the spread. In a January 6,

1992 inter-office memorandum, Baxter informs its employees how to respond to inquiries concerning AWP increases for Baxter products:

> If you receive inquiries from customers or payors questioning our rationale on this recent increase in Published AWP for Baxter products please communicate the following message and no more.
>
> If any further information is needed please send the inquiry to me directly.
>
> A recent review of industry published direct prices and AWPs revealed that Baxter's published AWPs are significantly lower than competitive AWPs. We have therefore adjusted our AWPs to meet competitive levels.
>
> Most of Baxter General Healthcare Division's products are sold to distributors at negotiated contract prices that are different from AWPs. We do not have knowledge of or input to the actual prices charged to the provider by our distributors. The contracted prices to our distributors will not be directly affected by this change in AWPs.

(BAX MDL 0004210) (Highly Confidential).

292. In addition, Baxter's marketing and sales documents, which were prepared and disseminated to its employees and agents via the U.S. mail and interstate wire facilities, compared the costs of their respective drugs to those of their respective competitors and were intended to induce physicians to use Baxter drugs and shift market share in its favor. Other documents created and disseminated by Baxter compared the AWP and the actual "cost" of their respective drugs, so that medical providers could easily see the different "return-to-practice" amounts available for different levels of purchase.

5. Specific Baxter AWPs Documented by the DOJ

293. In a report published by the DHHS (AB-00-86), the DOJ documented at least 41 instances where the published AWPs for various dosages of drugs manufactured by Baxter were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the four drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular